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| International Application Number | International Filing Date | International Earliest Priority Date |
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| PCT/US2004/037810 | 12 November 2004 (12.11.2004) | 12 November 2003 (12.11.2003) |

TITLE OF INVENTION: SYSTEM FOR TREATING AND PREVENTING BREAST CANCER
APPLICANT FOR DO/US: THERION BIOLOGICS CORPORATION, et al.

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (ORIGINAL) A method for inducing an immunological response against a cell expressing a breast cancer associated antigen in a human, said method comprising the steps of: selecting a human having breast cancer or at risk for developing such a breast cancer tumor, administering to the individual a first vector containing a first gene, or antigenic portion thereof, that encodes a breast cancer associated antigen, and at regular intervals thereafter administering at least a second vector containing a gene encoding a breast cancer associated antigen or antigenic portion thereof, wherein the second vector is from the same or a different source as the first vector.

2. (CURRENTLY AMENDED) The method of claim 1 ~~claim 1 or 2~~, further comprising administering at least one co-stimulatory molecule.

3. (CURRENTLY AMENDED) The method of claim 1 ~~or 2~~, further comprising administering granulocyte-macrophage colony stimulating factor (GM-CSF).

4. (ORIGINAL) The method of claim 2, wherein the co-stimulatory molecule is administered as a gene contained within the same vector as the vector containing gene encoding the breast cancer associated antigen.

5. (ORIGINAL) The method of claim 2, wherein the vector contains at least B7.1, LFA-3 and ICAM-1 as co-stimulatory genes.

6. (CURRENTLY AMENDED) The method according to claim 1 ~~claims 1-5~~, wherein said breast cancer associated antigen, or antigenic portion thereof, is contained in a pox virus vector.

7. (ORIGINAL) The method according to claim 7, wherein said pox virus vector is selected from the group consisting of : an orthopox virus vector; avipox virus vector; a suipox virus vector; a capripox virus vector; a leporipox virus vector; and an iridovirus vector.

8. (ORIGINAL) The method according to claim 6, wherein at least one of said pox virus vector is a replication impaired or non-replicating pox virus vector.

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9. (ORIGINAL) The method according to claim 7, wherein said first pox virus vector is an orthopox vector.

10. (ORIGINAL) The method according to claim 9, wherein said orthopox virus vector is Wyeth vaccinia, MVA or NYVAC.

11. (CURRENTLY AMENDED) The method of claim 7 ~~claims 1-10~~, wherein the breast cancer associated antigen is selected from the group consisting of carcinoembryonic antigen, mucin, HER-2/neu, uPA, NY-BR-1, NY-BR-62, NY-BR-85, antigenic portions thereof, and modified versions thereof.

12. (ORIGINAL) The method of claim 11, wherein the mucin is MUC-1.

13. (ORIGINAL) The method of claim 11, wherein the modified version thereof is a wobbled MUC and contains five to fifteen tandem repeats.

14. (CURRENTLY AMENDED) The method of claim 7 ~~claims 1-11~~, wherein the vectors contain genes encoding at least two breast cancer associated antigens or antigenic portions thereof.

15. (ORIGINAL) The method of claim 14, wherein the breast cancer associated antigens are CEA and a mucin.

16. (ORIGINAL) The method of claim 15, wherein the mucin is a wobbled MUC-1 or a wobbled mini-MUC-1 having six tandem repeats.

17. (CURRENTLY AMENDED) The method of claim 11 ~~claims 1-16~~, wherein one to three administrations at set intervals are made by an orthopox vector containing the at least one breast cancer associated antigen or antigenic portion thereof and multiple administrations at set intervals are made by an avipox vector containing the at least one breast cancer associated antigen or antigenic portion thereof.

18. (ORIGINAL) The method of claim 17, wherein the orthopox vector is vaccinia.

19. (ORIGINAL) The method of claim 18, wherein the vaccinia is vaccinia Wyeth or an attenuated vaccinia.

20. (ORIGINAL) The method of claim 19, wherein the attenuated vaccinia is MVA or NYVAC.

21. (CURRENTLY AMENDED) The method of claim 17 ~~claims 17, 18, 19 or 20~~, wherein the orthopox vector is administered before the avipox vector is administered.

22. (ORIGINAL) The method of claim 21, wherein the set interval is 20 days to 90 days.

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23. (ORIGINAL) A kit for enhancing a protective immune reaction against a breast cancer tumor comprising at least one pox vector encoding at least two breast cancer associated antigens or antigenic portion thereof.

24. (ORIGINAL) The kit of claim 23, wherein one breast cancer associated antigen is CEA and the at least second breast cancer associated antigen is a wobbled MUC-1 or a wobbled mini-MUC-1.

25. (NEW) An isolated nucleic acid molecule encoding a Muc-1 fragment sufficient to generate an immune reaction to Muc-1.

26. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment will not undergo extensive excision as a result of homologous recombination.

27. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment comprises from between about 5 to about 25 Muc-1 tandem repeat units.

28. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment comprises from between about 6 to about 15 Muc-1 tandem repeat units.

29. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment comprises from between about 6 to about 12 Muc-1 tandem repeat units.

30. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment comprises about 6 Muc-1 tandem repeat units.

31. (NEW) The isolated nucleic acid molecule of claim 25, wherein the Muc-1 fragment is wobbled.

32. (NEW) An isolated nucleic acid molecule encoding one or more of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof.

33. (NEW) A method for inducing an immunological response against a cell expressing a breast cancer associated antigen in an individual, comprising administering a therapeutically effective amount of a nucleic acid molecule encoding a Muc-1 fragment sufficient to generate an immune reaction to Muc-1.

34. (NEW) The method of claim 33, wherein the Muc-1 fragment will not undergo extensive excision as a result of homologous recombination.

35. (NEW) The method of claim 33, wherein the Muc-1 fragment comprises from between about 5 to about 25 Muc-1 tandem repeat units.

36. (NEW) The method of claim 33, wherein the Muc-1 fragment comprises from between about 6 to about 15 Muc-1 tandem repeat units.

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37. (NEW) The method of claim 33, wherein the Muc-1 fragment comprises from between about 6 to about 12 Muc-1 tandem repeat units.

38. (NEW) The method of claim 33, wherein the Muc-1 fragment comprises about 6 Muc-1 tandem repeat units.

39. (NEW) The method of claim 33, wherein the Muc-1 fragment is wobbled.

40. (NEW) A method for inducing an immunological response against a cell expressing a breast cancer associated antigen in an individual, comprising administering a therapeutically effective amount of one or more of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof.

41. (NEW) A kit for enhancing a protective immune reaction against a breast cancer tumor comprising one or more of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof and instructions for use.

42. (NEW) A kit for enhancing a protective immune reaction against a breast cancer tumor comprising one or more of an isolated nucleic acid molecule encoding a Muc-1 fragment sufficient to generate an immune reaction to Muc-1 and instructions for use.

43. (NEW) The kit of claim 42, wherein the Muc-1 fragment comprises from between about 5 to about 25 Muc-1 tandem repeat units.